DETAILED ACTION

Remarks

In the reply filed 02/13/2008, Applicants cancelled claims 45-56 and added claims 57-96.

Election/Restrictions

Applicant's election with traverse of Group I, original claims 1-44 and new claims 57-79, drawn to an antisense oligonucleotide derived from SEQ ID NO: 1 in the reply filed on 02/13/2008 is acknowledged. The traversal is on the ground(s) that Wright, *et al.* (U.S. Patent 6,121,000) does not break the unity of invention because the reference does not teach antisense oligonucleotides with at least 7 consecutive nucleotides of SEQ ID NO: 1. This is not found persuasive because the Wright, *et al.* reference precisely teaches SEQ ID NO: 1, as explained further in the following rejections.

The requirement is still deemed proper and is therefore made FINAL.

Applicant's election without traverse of species "prostate tumour" and "docetaxel" in the reply filed on 02/13/2008 is acknowledged. Applicants stated that the election was with traverse but provided no arguments supporting such traversal. Therefore, the election was made without traverse.

Claims 80-96 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction requirement in the reply filed on 02/13/2008.

Claims 3, 7-12, 15, 19, 20, 24, 25, 27, 36-38, and 40-44 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 02/13/2008.

Claim Objections

Claims 21-23, 26, 28-32, and 39 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). Accordingly, the claims have not been further treated on the merits.

Claims 1, 2, 4-6, 13, 14, 16-18, 33-35, and 57-79 are being examined on the merits.

Priority

Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 120 as follows: The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35

U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 60/320,210, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for one or more claims of this application. The nucleotide sequence corresponding to SEQ ID NO: 1 is not disclosed in Application No. 60/320,210. Thus, the instant claims receive the benefit of the filing date of PCT/CA04/00761, which is 05/21/2004.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 4-6, 13, 14, 16-18, and 33-35 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Wright, *et al.* (2000, U.S. Patent 6,121,000, Item A2 on 11/21/2005 IDS) (Wright).

The claims are to an antisense oligonucleotide between 7 and 100 nucleotides in length comprising at least 7 consecutive nucleotides from SEQ ID NO: 1. The claims are further to the oligonucleotide comprising one or more phosphorothioates.

Wright teaches SEQ ID NO: 176, which is identical to the instantly claimed SEQ ID NO: 1 (column 19, Table 3) and which may contain phosphorothioate internucleotide linkages (column 11, lines 30-42). Thus, Wright clearly anticipates the instant claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 4-6, 13, 14, 16-18, 33-35, and 57-76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright, *et al.* (2000, U.S. Patent 6,121,000) (Wright).

Claims 1, 2, 4-6, 13, 14, 16-18, and 33-35 are to the antisense oligonucleotide comprising SEQ ID NO: 1 as described above and to the oligonucleotide comprising phosphorothioates or other modified nucleotides. Claims 57-76 are to a dosage unit formulation comprising SEQ ID NO: 1 in an amount effective to provide specific doses to a human and a pharmaceutically acceptable carrier. Claims are also to the formulation further comprising one or more chemotherapeutics.

Wright teaches the instant SEQ ID NO: 176, which is identical to the instant SEQ ID NO: 1, comprising modified nucleotides, such as those with phosphorothioate linkages (described at the bottom of column 10 and at column 11, lines 30-42). Wright teaches that the oligonucleotide may be administered in conjunction with known chemotherapeutic agents (column 29, lines 14-17). At column 24, lines 38-62, Wright teaches the oligonucleotide formulated in a unit dosage form for administration to a human and that such dosages are understood to be determined by a physician. At column 23, lines 54-65, Wright teaches that compositions comprising the antisense oligonucleotide can be formulated for various routes of administration, such as by

intravenous injection, and that such compositions are prepared in a manner well known in the pharmaceutical arts. Wright does not explicitly teach the dosages of the instant claims.

It would have been obvious to one skilled in the art at the time of the instant invention to formulate the instant SEQ ID NO: 1 with a chemotherapeutic for the claimed modes of administration, as taught by Wright. It further would have been obvious to make such formulations in the instantly claimed dosages, because Wright teaches that appropriate dosages were well-known to be established by a physician. One would reasonably expect that such a formulation would be effective, because Wright teaches the precise SEQ ID NO: 1 (as SEQ ID NO: 176) for use with a chemotherapeutic agent and in formulations for various modes of administration at physician-determined dosages. Thus, the claims would have been obvious to one of skill in the art at the time of the instant invention.

Claims 1, 2, 4-6, 13, 14, 16-18, 33-35, and 57-79 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wright in view of Kosmas, *et al.* (2001, Cancer, v.92:2902-10) (Kosmas).

Claims 1, 2, 4-6, 13, 14, 16-18, 33-35, and 57-76 are to the antisense oligonucleotide formulations previously described. Claims 77-79 are to the oligonucleotide formulated with the chemotherapeutic agent, docetaxel.

Wright teaches oligonucleotide-chemotherapeutic formulations as described. Wright does not explicitly teach the chemotherapeutic, docetaxel.

Kosmas teaches Docetaxel as a chemotherapeutic agent (abstract).

It would have been obvious to one skilled in the art to formulate the antisense oligonucleotide comprising SEQ ID NO: 1 taught by Wright with docetaxel as taught by Kosmas because Wright teaches SEQ ID NO: 1 with known chemotherapeutic agents and Kosmas teaches that docetaxel was a known chemotherapeutic agent. Therefore, using docetaxel in the oligonucleotide-chemotherapeutic formulations taught by Wright is a matter of simple substitution of one known equivalent for another known to have the same function.

Double Patenting

Claims 57-79 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 161-175, 182, and 182 of copending Application No. 10/545,152. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are to dosage formulations and the claims differ only in the claimed dosage amounts. Application No. 10/545,152 discloses that dosages are determined by skilled practitioners (p.36, lines 9-13).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JENNIFER PITRAK whose telephone number is (571)270-3061. The examiner can normally be reached on Monday-Friday, 8:30AM-5:00PM, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached on 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Pitrak, PhD
Examiner
Art Unit 1635

/Tracy Vivlemore/
Primary Examiner, Art Unit 1635